REMARKS

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhard et al., U.S. Patent No. 6,331,174 ("Reinhard") in view of Kaufhold, Jr. et al., U.S. Patent No. 5,125,898 ("Kaufhold").

The Office characterizes Reinhard as disclosing the basic inventive concept of the present application of a prefilled syringe with the exception of using a luer tip for connection of the injection needle. The Office cites Kaufhold as showing the use of a luer lock tip. The position of the Office is that it would have been obvious to a person of ordinary skill in the art to modify the syringe of Reinhard to use a luer tip of Kaufhold in connection with the seal/gasket to force the needle inside the plunger for added safety.

Applicants respectfully submit that the combination of Reinhard and Kaufhold proposed by the Office will not result in the prefilled syringe of the present application.

Reinhard discloses a body of a prefilled syringe with a barrel, grip and nozzle which is made of a transparent, glass-like plastic with very low gas permeability. However, in addition to not disclosing a luer tip, Reinhard also does not disclose a gas permeable intermediate layer and the location of the intermediate

layer of the present invention as recited in the claims of the present application.

The advantage of the present invention depends on a multilayer structure in which the intermediate layer is composed of a layer made of a resin excelling in a barrier property, i.e., an oxygen and/or water vapor barrier property.

The innermost and outermost layers 15, 16 in the present invention are not necessarily a barrier to oxygen or water vapor, while the inner and outer layers 9, 10 in Reinhard are good barriers to oxygen or water vapor. The intermediate layer 17 in the present invention is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor barrier property. The middle layer 14 in Reinhard is an inorganic layer of metallic, ceramic or glassy materials, such as SiO_x, SiO_xC_y and TiO_x, which acts as a diffusion barrier (see col. 6, lines 28 to 31). The inorganic layer is used in lieu of a layer of a plastic resin.

The Office cites col. 5, line 25, of Reinhard as disclosing an intermediate layer made of a resin excelling in an oxygen and/or water vapor property. However, this is a description of the walls of the barrel of the syringe of Fig. 1 of Reinhard, which is a single layer construction and cannot be interpreted as describing an intermediate layer.

Claims 1 and 3 have been amended to precisely recite that the intermediate layer is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor barrier property. This amendment is only a restatement of recitations present in claims 1 and 3 and does not change the scope of the claims or otherwise introduce new limitations or raise new issues.

Reinhard also fails to disclose the location of the intermediate layer as required by the claims of the present application. The location of the intermediate layer in the present application is material for the prevention of deterioration of a medication caused by oxygen and evaporation of water.

Regarding claim 1 of the present application, the intermediate layer 17 is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel. As described in paragraph [0022] of the specification of the present application, "[i]n the space from the proximal end 30a of the gasket 30 to the proximal end 10a of the barrel 10, a medicament does not exist. Therefore, there is no need to provide a barrier property."

Reinhard discloses that the intermediate layer is formed <u>from the proximal end</u> of the barrel 1 to the distal end of the barrel 1

(see, Fig. 3A, intermediate layer 14 is up to the proximal end of the grip 2).

Additionally, as recited in claim 1, the prefilled syringe in the present invention comprises a shoulder portion provided with a luer tip, and the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip (see Figs. 1 and 2). However, the device of Reinhard does not include a luer tip and, therefore, Reinhard cannot meet this limitation. And, as noted above, in the device of Reinhard the intermediate layer is formed from the proximal end of the barrel 1 only to the distal end of the barrel 1.

Regarding claim 3, the end of the intermediate layer 17 in a cylindrical wall portion of the barrel 10 is formed up to a rim of the shoulder portion and the shoulder portion has a thickness sufficient to exert an oxygen and/or water vapor barrier property. Reinhard does not disclose or suggest these limitations.

Also, according to claim 3, the luer tip is sealed by a cap having a barrier property. Reinhard does not disclose a luer tip and a cap that seals the luer tip.

For the above reasons, the proposed modification of Reinhard will not result in the prefilled syringe of the present invention and the 35 U.S.C. § 103(a) rejection cannot stand.

Regarding the proposed modification of the device of Reinhard, the shoulder portion 13 of the prefilled syringe of the present invention is provided with a luer tip 11 arranged to be connected to an injection needle 70 at a tip thereof. In Reinhard, on the other hand, the needle 6 is integrated with the shoulder portion and a luer tip is not provided. Applicants respectfully submit that the prior does not provide a motivation to a person of ordinary skill in the art to modify the prefilled syringe of Reinhard to include the luer lock of Kaufhold.

Referring to Kaufhold, a luer lock assembly is mounted within the barrel of the syringe and the disposable medicinal syringe is not a prefilled syringe. Moreover, the luer lock assembly in Kaufhold which includes luer thread busing 30 and luer taper seal projection member 30 is not integrated with a barrel 12 (see col. 6, lines 36-38).

On the other hand, the invention of Reinhard is a preassembled unit consisting of a barrel with an integrated needle and that is used for injecting preparations with a fill volume of less than 5 ml. Modification of the prefilled syringe of Reinhard to include the separate luer lock assembly of Kaufhold which includes luer thread busing 30 and luer taper seal projection member 30 tip would

destroy the invention of Reinhard and, therefore, is not an obvious modification of Reinhard within the meaning of 35 U.S.C. § 103(a).

Removal of the 35 U.S.C. 103(a) rejection of the claims is believed to be in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated June 13, 2007, and is believed to place this application in condition for allowance.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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